

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
EASTERN DIVISION

No. 4:13-CV-76-H

ROBERTA SPILKER, Individually)
and as Executrix of the Estate of)
FRANKLIN J. SPILKER, JR., deceased,)
)
Plaintiffs,)
)
v.)
)
MEDTRONIC, INC., and MEDTRONIC)
CRYOCATH LP,)
)
Defendants.)

ORDER

The instant matter is before the court on Plaintiff's Motion to Extend Discovery [DE-69], Plaintiff's First Motion to Compel Discovery [DE-72], and Defendants' Motion for a Court Determination that Volume I of the Cryocatheter System's Pre-Market Approval Application is Properly Designated as Highly Confidential [DE-75]. The parties have filed their respective responses [DE- 71, -81, -84]. The court held a telephonic status conference on December 19, 2014, regarding Plaintiff's request to extend the discovery deadlines [DE-73], and at the court's request the parties filed a joint status report [DE-90] on March 18, 2015. Accordingly, the motions are ripe for decision.

For the reasons that follow, Plaintiff's Motion to Extend Discovery is allowed in part and denied in part, Plaintiff's First Motion to Compel Discovery is allowed in part and denied in part, and Defendants' Motion for a Court Determination that Volume I of the Cryocatheter System's Pre-Market Approval Application is Properly Designated as Highly Confidential is allowed.

I. BACKGROUND

On March 25, 2013, Defendants removed this action to this court from Beaufort County Superior Court. [DE-1]. Plaintiff Roberta Spilker (“Plaintiff”) filed this action individually and as Executrix of the Estate of Franklin J. Spilker, Jr., (“Decedent”) against Defendants as a result of Decedent’s death following a cardiac cryoablation, a medical procedure performed by medical personnel at Vidant Medical Center (“Vidant”) using a medical device manufactured and marketed by Defendants. [DE-1-2]. On May 23, 2013, Plaintiff filed a first amended complaint [DE-22], and on June 13, 2013, Defendants filed a motion to dismiss [DE-23]. After the court denied Defendants’ motion to dismiss [DE-31] and Defendants answered the amended complaint [DE-35], the court entered a scheduling order, which provided in relevant part: fact discovery to be concluded by December 16, 2014; expert discovery to be concluded by March 31, 2015; reports from Plaintiff’s retained experts due by December 16, 2014, from Defendants’ retained experts by February 1, 2015, and from rebuttal experts by March 1, 2015; dispositive motions to be filed by April 30, 2015; and the pretrial conference to be held during Senior Judge Howard’s August 17, 2015 civil term of court. [DE-38]. On July 24, 2014, the parties filed a proposed Discovery Plan for ESI [DE-54], which the court adopted [DE-55].

On June 6, 2014, Plaintiff filed a motion to quash a subpoena to third-party Vidant [DE-48], which the court denied [DE-60]. On August 26, 2014, Plaintiff filed a motion for an extension of the ten page limit applicable to motions to compel, which was denied without prejudice. [DE-56, -59]. On October 24, 2014, Defendants filed a motion to compel third-parties Vidant and ECRI to produce certain documents. [DE-62]. The court allowed the motion [DE-82], and Vidant and ECRI filed an appeal of that decision [DE-86], which is currently pending before the district judge.

On December 5, 2014, Plaintiff filed the instant motion to extend the discovery and other case deadlines. [DE-69]. On December 16, 2014, Plaintiff filed a motion for leave to file a second amended complaint [DE-70], which was allowed [DE-83, -85]. On December 19, 2014, Plaintiff filed the instant motion to compel discovery. [DE-72]. On December 23, 2014, Defendants filed the instant motion for confidentiality determination [DE-75] and the following day filed a motion to seal [DE-78]. On March 12, 2015, the court directed the parties to file a Joint Status Report advising the court as to whether any of the issues had been resolved, the status of discovery, and a proposed revised schedule for moving the case forward, and on March 18, 2015, the parties filed their report [DE-90].

II. DISCUSSION

A. Plaintiff's First Motion to Compel Discovery [DE-72]

Plaintiff moves the court for an order (1) directing Defendants to provide an index for documents produced in discovery indicating by Bates Number the documents responsive to each particular request, and (2) finding Defendants have waived the privileges claimed (i) in Defendants' September 29, 2014 and December 2, 2014 privilege logs, (ii) in Defendants' responses to Plaintiff's Second, Third, and Fourth sets of Requests for Production of Documents ("RFP"), and (iii) in Defendants' objection to RFP No. 14 from Plaintiff's first set of document requests. Pl.'s Mot. [DE-72] at 4-10. Defendants contend they produced documents as they were kept in the usual course of business and complied with the parties' ESI protocol, the privilege logs are compliant, and any delay in producing a privilege log is attributable to Plaintiff. Defs.' Mem. [DE-81] at 2-10.¹

¹ The page numbers related to Defendants' memorandum in opposition reference those assigned by the court's CM/ECF filing system, which differ from the document's internal page numbers.

i. Document Production

The court first addresses the timeliness of Plaintiff's motion to compel with respect to Defendants' document production. While Rule 37(a) governing motions to compel does not specify a temporal requirement for the filing of such motions, "[g]enerally, absent a specific directive in the scheduling order, motions to compel discovery filed prior to the discovery deadline have been held timely." *PCS Phosphate Co. v. Norfolk S. Corp.*, 238 F.R.D. 555, 558 (E.D.N.C. 2006) (citations omitted). Whether to grant or deny a motion to compel is generally left within the district court's "substantial discretion in managing discovery." *Lone Star Steakhouse & Saloon, Inc. v. Alpha Va., Inc.*, 43 F.3d 922, 929 (4th Cir. 1995).

Fact discovery closed on December 16, 2014, and Plaintiff filed her motion to compel three days later. [DE-38, -72]. Plaintiff served her first set of discovery requests on March 13, 2014, Pl.'s First Interrogs. & RFPs [DE-72-4], and Defendants responded on April 14, 2014, Defs.' Resp. [DE-72-5, 72-6]. On May 7, 2014, Plaintiff's counsel sent a letter to Defendants' counsel detailing numerous perceived discovery deficiencies, including Defendants' failure to provide a privilege log and failure to provide an index indicating by Bates Number the documents responsive to each request. May 7, 2014 Letter from J. Parrish to A. Littmann [DE-72-7] at 3-4, 11. Notably, while specifically taking issue with more than twenty of Defendants' RFP objections, Plaintiff did not specifically address Defendants' response to RFP No. 14. *Id.* at 12. On May 15, 2014, Defendants' counsel responded by letter to Plaintiff's counsel, indicating that Defendants had produced the documents in the manner requested by Plaintiff and that Defendants would provide a privilege log at the conclusion of their document production. May 15, 2014 Letter from A. Littmann to J. Parrish [DE-72-8] at 3-5. Between June 27, 2014 and July 1, 2014, counsel engaged in further email

communications regarding an ESI protocol and Defendants' failure to produce an index indicating by Bates Number the documents responsive to each request. Emails Regarding Production Format [DE-72-9]. Defendants' counsel made clear that "we will not provide a comprehensive document index, which you requested only after we made our first document production." *Id.* at 7. Thus, the issues raised in Plaintiff's motion to compel were ripe as early as May 15, 2014, and it was evident by July that Defendants would not change their position. Yet, Plaintiff did not bring the motion to compel for nearly six months, while Defendants continued to produce nearly 500,000 pages in the same manner.

Moreover, Plaintiff's assertion that she attempted to bring all pending matters to the court's attention in August 2014 does not excuse her failure to timely raise these issues. On August 26, 2014, Plaintiff filed a motion for an extension of the ten page limit applicable to motions to compel. [DE-56]. Defendants opposed the motion on the grounds that it was premature because Plaintiff had yet to comply with the meet and confer requirements of Local Civil Rule 7.1(c) and Rule 37(a)(1). [DE-58]. On September 15, 2014, the court denied the motion *without prejudice* on the ground that the information Plaintiff sought to include in its memorandum was typically filed as an exhibit, further noting that it appeared the parties had not engaged in the requisite meet and confer and that substantive discussions may narrow the issues and obviate the need for a lengthy memorandum. [DE-59]. The court's order presented no bar to Plaintiff filing her motion to compel. Plaintiff also asserts that Defendants then promised to "produce documents at unspecified times in the future, including a promise to produce a privilege log at some point." Pl.'s Mot. [DE-72] at 3. However, there is no indication that Defendants ever promised to produce the index Plaintiff first sought in May of 2014, and if Plaintiff was unsatisfied with Defendants' response, she could have promptly

filed a motion to compel at that time rather than waiting several months until after the close of discovery.

Finally, Defendants would be prejudiced by allowing the relief sought. The issues raised by Plaintiff were apparent after Defendants responded to Plaintiff's first document requests in April of 2014, yet Plaintiff failed to bring these issues to the court while Defendants continued to produce documents on a rolling basis and to respond to further discovery requests in the same purportedly deficient manner. Now with fact discovery completed, it would be unreasonable to require Defendants to go back and index nearly 500,000 pages and to find their privileges waived when these issues could have been addressed early on in discovery. *See English v. Johns*, No. 5:11-CT-3206-D, 2014 WL 555661, at *4 (E.D.N.C. Feb. 11, 2014) (unpublished) (denying as untimely motion to compel filed after the close of discovery), *aff'd*, 582 F. App'x 229 (4th Cir. 2014); *Sager v. Standard Ins. Co.*, No. 5:08-CV-628-D, 2010 WL 2772433, at *1 (E.D.N.C. July 12, 2010) (unpublished) (denying as untimely motion to compel filed three weeks after the close of discovery where plaintiff provided no reason for the delay and failed to show good cause for the court to "essentially amend its Scheduling Order to reopen fact discovery."). Accordingly, because Plaintiff failed to timely bring her motion to compel before the court and failed to demonstrate good cause for the delay, Plaintiff's motion to compel as to Defendants' document production is denied.

Alternatively, Plaintiff's motion as to the document production fails on the merits. Plaintiff first contends that Defendants engaged in a document dump and failed to comply with Rule 34 when producing documents. Pl.'s Mot. [DE-72] at 4-7. By example, Plaintiff points out that Volume I of the CryoCatheter System PMA application falls after Volume 25 in Bates Number sequence and that Defendants' June 4, 2014 document production contained 8,672 documents that were "not in

order by subject matter, topic, or anything similar.” *Id.* at 5.

“A party must produce documents as they are kept in the usual course of business or must organize and label them to correspond to the categories in the requests” Fed. R. Civ. P. 34(b)(2)(E)(i). A producing party need not organize and label documents kept in the usual course of business, because a business presumably would keep its documents organized “in a way that maximizes their usefulness in the day-to-day operations of the business.” *In re Sulfuric Acid Antitrust Litig.*, 231 F.R.D. 351, 363 (N.D. Ill. 2005). “A party demonstrates that it has produced documents in the usual course by revealing information about where the documents were maintained, who maintained them, and whether the documents came from one single source or file or multiple sources or files.” *Enargy Power (Shenzhen) Co. v. Xiaolong Wang*, No. CIV.A. 13-11348-DJC, 2014 WL 4687542, at *4 (D. Mass. Sept. 17, 2014) (unpublished) (quoting *Valeo Elec. Sys., Inc. v. Cleveland Die & Mfg Co.*, No. 08-CV-12486, 2009 WL 1803216, at *2 (E.D. Mich. June 17, 2009) (unpublished) (citation omitted)). A party which opts to produce documents as maintained in the usual course of its business bears the burden of demonstrating that the documents were produced in this manner. *Stillwagon v. Innsbrook Golf & Marina, LLC*, No. 2:13-CV-00018-D, 2014 WL 1652562, at *4 (E.D.N.C. Apr. 23, 2014) (unpublished) (citing *DE Techs, Inc. v. Dell, Inc.*, 238 F.R.D. 561, 566 (W.D.Va. 2006)).

Here, Defendants assert that the documents, most of which came from ESI, were produced as kept in the usual course of business and that they “organized file folders by custodian and provided [Plaintiff] searchable documents with metadata.” May 15, 2014 Letter from A. Littmann to J. Parrish [DE-72-8] at 4. Defendants’ counsel provided Plaintiff’s counsel with the following detailed description of the organization of its production:

We have already provided you many of the design documents and FDA documents you are seeking and complain about below. These can be found through the CryoCatheter System's PMA File in folders 14, 17, and 23 of the document production. You can find documents from Medtronic's investigation into this matter in folders 15 and 20. We have started to produce documents related to Ann Munoz, which can be found in folders 22 and 26; we will continue to produce more as we get it. We have also produced many of the training documents you seek in folder 24. Folder 19 contains documents related to the design and development of the FlexCath Sheath, including 510k documents. These are just the highlights. A skimming of the folders that contain our document production would have alleviated many of the concerns you list below.

You have all the information you need – the metadata and searchable files and a folder structure – to efficiently search and review Medtronic's document production. Indeed, the folder information provided in the ".opt" file that is included in the production provides you the location (folder) of each produced document. It lists the Start Bates along with the corresponding folder number. The ".lfp" and ".opt" files when used properly to load the documents into a standard, commercially available document review platform would allow for Medtronic's documents to be properly lined up with the metadata provided within the ".dat" file. If this capability still is not enough for you, we can offer to provide you an overlay file with the "original folder path" information and the corresponding bates number. But again, you specifically requested that we produce single, searchable PDF files with metadata, and that is precisely what we did. We went even further than your request and organized the documents into folders that correspond with custodians. You now have the same opportunity that we have to search and review these documents.

Id. Defendants provided Plaintiff with fully searchable documents, sortable by metadata fields, in a folder structure organized by custodian. This is sufficient to satisfy the requirements for document production of ESI under Rule 34. *See Lutzeier v. Citigroup Inc.*, No. 4:14-CV-00183-RLW, 2015 WL 430196, at *8 (E.D. Mo. Feb. 2, 2015) (unpublished) (finding production complied with Rule 34 where it was "in a reasonably usable form or forms and/or the production is searchable, sortable and paired with relevant metadata."); *cf. Indep. Mktg. Grp., Inc. v. Keen*, No. 3:11-CV-447-J-25MCR, 2012 WL 207032, at *2 (M.D. Fla. Jan. 24, 2012) (unpublished) (finding producing party failed to produce documents as ordinarily kept where it printed documents from its server and scanned them

into digital form, rendering non-searchable PDF files) (citing *Bray & Gillespie Mgmt. LLC v. Lexington Ins. Co.*, 259 F.R.D. 568, 585-86 (M.D. Fla. 2009) (documents kept on a computer and gathered electronically by creating files without metadata “for the sole purpose of producing them” is not “ESI as kept in the usual course of business”)).

Likewise, Defendants produced the documents as requested by Plaintiff and as agreed to later in the parties’ ESI Discovery Plan. *See* Apr. 28, 2014 Email from W. Grant to A. Littmann [DE-81-4] (“Please produce documents in searchable PDF format with metadata. We prefer that each multi-page document be produced as an individual file (instead of separate files for each page of the document).”); Discovery Plan for ESI [DE-54] at 5. *See Lutzeier*, 2015 WL 430196, at *8 (denying motion to compel where producing party complied with both Rule 34 and the parties’ ESI agreement). Furthermore, it is unclear what steps Plaintiff has taken to manage and review the ESI produced by Defendants. For example, Plaintiff has made no assertion that Defendants’ production is not fully searchable and sortable utilizing the metadata fields as Defendants claim. *See Nat’l Jewish Health v. WebMD Health Servs. Grp., Inc.*, No. 12-CV-02834-WYD-MJW, 2014 WL 2118585, at *5-7 (D. Colo. May 21, 2014) (denying motion for sanctions and finding ESI production complied with Rule 34 where movant “offered no evidence of an inability to search or sort the [] ESI Production and, in fact, offered no evidence that [movant] ever attempted to search or sort the [] ESI Production” and “[movant] did not present any evidence that it performed any searches of the [] ESI Production using any document review platform.”). Accordingly, Defendants have satisfied their obligations under Rule 34 and the ESI Discovery Plan, and the court will not require Defendants to provide an index.

ii. Attorney-Client Privilege and Work-Product

Plaintiff contends that Defendants' have broadly asserted attorney-client privilege and the work-product doctrine without making any showing that those privileges apply or identifying whether documents have been withheld. Pl.'s Mem. [DE-72] at 7-8. Specifically, Plaintiff points to Defendants' responses to Plaintiff's Second, Third, and Fourth Requests for Production, in which Defendants asserted general objections on the basis of privilege. Defs.' Resp. to RFPs [DE-72-11 to -72-13]. However, subsequent to these responses, Defendants produced a privilege log on September 29, 2014, and after completing their document production they produced a supplemental privilege log on December 2, 2014. [DE-72-10, 72-14]. Thus, Plaintiff now knows which documents have been withheld.

Plaintiff next contends that the privilege logs were untimely and that Defendants have thus waived the privilege asserted. Defendants made a rolling production, and it is apparent from certain email correspondence, *see, e.g.*, April 15–27, 2014 Emails [DE-71-5], June 13–14, 2015 Emails [DE-71-6], Aug. 2015 Emails [DE-71-8], that much of the delay was attributable to Plaintiff's own failure to finalize the ESI plan and provide Defendants with search terms. *See Westdale Recap Properties, Ltd. v. NP/I & G Wakefield Commons, L.L.C.*, No. 5:11-CV-659-D, 2013 WL 5424844, at *4 (E.D.N.C. Sept. 26, 2013) (unpublished) (finding a “determination of waiver based on tardiness would be unduly harsh and is not warranted” where the delay in producing a privilege log was due to the producing party awaiting agreement on a protocol for ESI and proposed search terms from the requesting party). Further, Defendants notified Plaintiff in May of 2014 that they would produce a privilege log at the conclusion of the document production. May 15, 2014 Letter from A. Littmann to J. Parrish [DE-72-8] at 5. If Plaintiff was dissatisfied with Defendants' position, she should have

promptly brought the issue to the court's attention rather than waiting several months. Thus, under the circumstances presented here, it would be unfair to impose the harsh sanction of waiver based on untimeliness.

Plaintiff next contends that the privilege logs are insufficient in that they do not provide sufficient information to determine whether documents are work-product or routine business documents. Pl.'s Mot. [DE-72] at 8-10. "The attorney-client privilege exists when (1) there is an attorney-client relationship, (2) the communication in question relates to a fact that the attorney learned from the client, outside the presence of strangers, for the purpose of securing a legal opinion or legal services, and (3) the privilege has been claimed and not waived." *Yerger v. Liberty Mut. Grp., Inc.*, No. 5:11-CV-238-D, 2012 WL 4424017, at *5 (E.D.N.C. Sept. 24, 2012) (unpublished) (citing *Hawkins v. Stables*, 148 F.3d 379, 383 (4th Cir. 1998)). "To validly claim a privilege, a party must expressly assert it in response to the particular discovery request involved and serve with its discovery responses a privilege log in conformance with Rule 26(b)(5)(A)." *Rohlik v. I-Flow Corp.*, No. 7:10-CV-173-FL, 2012 WL 1596732, at *4 (E.D.N.C. May 7, 2012) (unpublished). "'When a party relies on a privilege log to assert these privileges [i.e., attorney-client privilege and work product protection], the log must as to each document . . . set [] forth specific facts that, if credited, would suffice to establish each element of the privilege or immunity that is claimed.'" *Id.* (internal quotation marks and citation omitted).

Here, the privilege logs provide the following information for each document withheld: date, author, recipient (including any recipient copied or blind copied), description, and the privilege asserted. Privilege Logs [DE-72-10, -72-14]. The supplemental log also includes a glossary of names and titles associated with the documents for which privilege was asserted. [DE-72-14]. The

descriptions provided by Defendants are sufficiently specific to allow Plaintiff to determine the basis for the privilege asserted with respect to each document. *See Rohlik*, 2012 WL 1596732, at *4 (holding that privilege log providing the Bates number, type of document, date, privilege asserted, summary, author, and recipient was sufficient to meet the “burden of establishing that the attorney-client relationship existed with respect to each of the documents in question and that they discuss or otherwise relate to defendant’s securing legal opinions.”). For example, it is apparent from the descriptions provided that the first three documents on Defendants’ privilege log are subject to attorney-client privilege because they are between counsel and client for the purpose of obtaining legal advice. *See* Sept. 29, 2014 Privilege Log [72-10] (Doc. 1 Description: “Memo made at direction of counsel and sent to counsel for purpose of seeing legal advice regarding medical procedure”; Doc. 2 Description: “[REDACTED] Email requesting advice of counsel regarding FDA request. Produced at MDT0370513.”; Doc. 3 Description; “Email requesting advice of counsel regarding FDA request.”). Accordingly, Defendants’ privilege logs are sufficiently specific.

Plaintiff next contends that Defendants have withheld investigation documents that were created in the ordinary course of business. Pl.’s Mot. [DE-72] at 8-9. The work product doctrine protects against the disclosure of certain materials “prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party’s attorney, consultant, surety, indemnitor, insurer, or agent).” Fed. R. Civ. P. 26(b)(3)(A). In determining whether a document is entitled to work-product protection, the court must consider whether “the ‘primary motivating purpose’ behind the performance of the work was to assist in the pending or impending litigation.” *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 143 F.R.D. 611, 617 (E.D.N.C. 1992) (quoting *In re Minebea Co.*, 143 F. Supp. 494, 498 (S.D.N.Y. 1992)). However, “the pure work product of an

attorney insofar as it involves ‘mental impressions, conclusions, opinions, or legal theories . . . concerning the litigation’ is immune to the same extent as an attorney-client communication.” *Nat’l Union Fire Ins. Co. of Pittsburgh, Pa. v. Murray Sheet Metal Co.*, 967 F.2d 980, 984 (4th Cir. 1992) (citation omitted). “If opinions and theories about the litigation are only part of a document otherwise discoverable, the court may require production of a redacted copy.” *Id.* at 985.

Plaintiff is correct that any documents created in the ordinary course of business rather than for litigation purposes are not subject to work-product protection. The court addressed this issue in Defendants’ motion to compel the production of the ECRI Report and supporting documentation from Vidant. [DE-62, -82]. In that motion, Defendants argued that investigation documents withheld by Vidant were not entitled to work-product protection because they were created pursuant to internal hospital policy and regulatory requirements rather than for litigation purposes. Defs.’ Mem. [DE-63] at 6-10. The court agreed, finding that “the documents themselves indicate that they were created in the ordinary course of business primarily for quality control purposes.” Jan. 6, 2015 Order [DE-82] at 8. This ruling applies with equal force here to any investigation documents Defendants created pursuant to internal policy or regulatory requirements rather than for litigation purposes. However, while investigation documents, if created for non-litigation purposes, would not themselves be entitled to attorney-client privilege or work-product protection, any attorney-client communications for the purpose of providing legal advice and any pure opinion work product (i.e., mental impressions, conclusions, opinions, or legal theories of counsel) found within those documents would remain protected. *See, e.g., Yerger*, 2012 WL 4424017, at *6 (“[F]act-finding which is necessary to the provision of legal advice is worthy of the attorney-client privilege.”) (citing *Upjohn Co. v. United States*, 449 U.S. 383, 390 (1981) (“[T]he privilege exists to protect not only

the giving of professional advice to those who can act on it but also the giving of information to the lawyer to enable him to give sound and informed advice.”); *F.C. Cycles Intern., Inc. v. Fila Sport*, 184 F.R.D. 64, 70-71 (D. Md. 1998) (“Communications between corporate counsel and company personnel are privileged so long as the information is relayed for the purpose of obtaining legal advice.”)).

There is some indication that Defendants appropriately applied these rules to their document production. For example, Defendants point to entry 28 on the September 29, 2014 privilege log, which is an attachment to an email sent to counsel. [DE-72-10]. The email at entry 26 was sent to one of Defendants’ attorneys for the purpose of obtaining the advice of counsel regarding the “Spilker incident.” *Id.* at 3. Defendants claimed attorney-client privilege with respect to the email and the portion of the attached document seeking legal advice. *Id.* However, Defendants redacted the privileged content and produced the remainder of the document, which included the written notes from the onsite investigation at Vidant of the Defendants’ equipment used in Decedent’s procedure. [DE-81-5]. Similarly, entries eight and nine are documents authored by non-attorneys attached to an email sent to an attorney and seeking advice of counsel. [DE-72-10]. The description for these entries indicates they contain “incident investigation information material collected to aid counsel to give advice.” *Id.* Defendants properly claimed attorney-client privilege with respect to the email seeking advice of counsel as well as the information collected to enable counsel to provide informed advice. *See Yerger*, 2012 WL 4424017, at *6 (finding defendant had met its burden of establishing that an attorney-client relationship existed and that the documents in question relate to facts that the attorney learned from the client for the purpose of securing a legal opinion, and the fact that non-attorneys were among those responsible for compiling the data did not prevent the attorney-client

privilege from applying) (citing *Upjohn Co.*, 449 U.S. at 391).

Notwithstanding the evident compliance with respect to some documents, there may yet be investigation documents that have been wrongfully withheld as work-product that were created for regulatory compliance or other non-litigation purposes and are not entirely protected by attorney-client privilege. Accordingly, no later than **April 22, 2015**, Defendants shall review the documents withheld under claims of attorney-client privilege or work-product and produce to Plaintiff any documents created in the ordinary course of business, for regulatory compliance, or for other non-litigation purposes, with appropriate redaction of attorney-client communications or pure opinion work product. Defendants shall also provide a revised privilege log reflecting the subsequent production of any entry and certify to Plaintiff that they have conducted the requisite review and that all responsive, non-privileged documents have been produced. Thereafter, Plaintiff shall by no later than **May 1, 2015**, meet and confer with Defendants regarding any entry for which Plaintiff still has questions regarding the claimed privilege. In the event the parties are unable to resolve a dispute with respect to any withheld document, Plaintiff shall notify Defendants of the challenged entries and Defendants by no later than **May 8, 2015**, shall submit those documents (including any related documents) by mail to the undersigned's chambers for in camera review.

iii. RFP No. 14

Plaintiff specifically addresses RFP No. 14 from her First Set of Requests for Production, seeking the protocol Defendants used to inspect and test the FlexCath® Steerable Sheath, which Plaintiff believes has been withheld under a claim of privilege, and moves the court to overrule Defendants' objection to the request and order the documents produced. Pl.'s Mot. [DE-72] at 10. Defendants contend that they have produced documents responsive to RFP No. 14, they have

produced non-privileged documents from the investigation of the procedure, they are unclear as to what exact documents Plaintiff is seeking when she asks for “protocols,” and Plaintiff has never discussed this particular RFP with Defendants. Defs.’ Mem. [DE-81] at 11.

It appears to the court that the only testing of the equipment used in Decedent’s procedure was done by Vidant with the assistance of Medtronic. Defs.’ Mem. [DE-71] at 8, n.2. It is, therefore, unclear whether the “protocols” Plaintiff seeks are in the possession of Vidant or Medtronic. To the extent Medtronic is in possession of the relevant documents, any claim that “protocols” related to this testing are privileged is met with scepticism where they were utilized for testing the equipment in conjunction with Vidant, a third-party potentially adverse to Medtronic. Nonetheless, given the lack of clarity on Defendants’ part as to precisely what “protocol” documents Plaintiff seeks, further meet and confer on this issue is necessary. Moreover, to the extent Defendants have withheld as privileged the documents Plaintiff seeks, the resolution of the issue is subsumed by the court’s direction above with respect to other documents withheld under a claim of privilege.

Finally, the court declines to award expenses, including attorney’s fees, related to brining or defending the motion, where the parties’ positions are substantially justified. Fed. R. Civ. P. 37(a)(5).

B. Plaintiff’s Motion to Extend Discovery [DE-69]

Plaintiff seeks to extend all case deadlines by 120 days. Pl.’s Mot. [DE-69] at 1. Plaintiff contends that additional time for fact discovery is necessary because Plaintiff’s expert cannot inspect the equipment used in Decedent’s procedure without knowing the testing protocol used during Medtronic and Vidant’s prior inspection of the equipment. *Id.* at 7. Plaintiff also asserts that some

third-party discovery may be necessary. *Id.* at 6. Defendants contend that Plaintiff's failure to complete discovery is due to her own delay and Plaintiff has failed to show good cause to alter the Scheduling Order. Defs.' Mem. [DE-71] at 1-3.

"A schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4). "[T]he touchstone of 'good cause' under Rule 16(b) is diligence." In other words, the focus of the 'good cause' inquiry is 'on the diligence of the party seeking modification of the scheduling order.'" *Neighbors Law Firm, P.C. v. Highland Capital Mgmt., L.P.*, No. 5:09-CV-352-F, 2011 WL 238605, at *2 (E.D.N.C. Jan. 24, 2011) (unpublished) (quoting *Dilmar Oil Co. v. Federated Mut. Ins. Co.*, 986 F. Supp. 959, 980 (D.S.C. 1997), *aff'd*, 129 F.3d 116 (4th Cir. 1997)). "Rule 16(b)(4) expressly limits modification of scheduling orders to good cause and thus does not permit alteration of deadlines based upon a showing of extraordinary circumstances or in the interest of justice." *Id.* (quoting *Halpern v. Wake Forest Univ. Health Scis.*, 268 F.R.D. 264, 273 (M.D.N.C. 2010)) (internal quotation marks omitted). "Thus, a court may 'modify the schedule on a showing of good cause if [the deadline] cannot be met despite the diligence of the party seeking the extension.'" *Id.* (quoting Fed. R. Civ. P. 16(b) advisory committee's note to 1983 amendment).

While many of the issues Plaintiff raised in the motion to compel that form the basis for the requested extension of deadlines could have been brought to the court earlier, the key issue with respect to the investigation and protocol documents was not fully developed until production of Defendants' December 2, 2014 privilege log. Furthermore, given the court's ruling on Plaintiff's motion to compel, the court finds that some extension of the case deadlines is warranted. Therefore, for good cause shown, Plaintiff's motion for extension of time is allowed in part and denied in part, and the Scheduling Order is amended as follows:

1. All discovery shall be commenced in time to be concluded by no later than **June 28, 2015**;
2. Reports from retained experts under Fed. R. Civ. P. 26(a)(2) are due as follows: from Plaintiff(s) by **July 28, 2015**; from Defendant(s) by **August 27, 2015**; from Plaintiff(s) for rebuttal experts by **September 28, 2015**;
3. All potentially dispositive motions shall be filed by no later than **October 28, 2015**; and
4. This action will be calendared for trial before Judge Malcolm J. Howard in Greenville. This matter will be scheduled for final pretrial conference during Judge Howard's **February 16, 2016** civil term. A specific trial date will be set at or following the pretrial conference, with trial to commence no sooner than two (2) weeks after the pretrial conference.

The remaining provisions of the Scheduling Order not altered herein remain in effect.

C. Defendants' Motion for a Court Determination that Volume I of the Cryocatheter System's Pre-Market Approval Application is Properly Designated as Highly Confidential [DE-75]

Defendants seek a court determination that Volume I of the Cryocatheter System's Pre-Market Approval Application ("PMA") is properly designated as highly confidential. [DE-75]. Defendants filed the motion because Plaintiff's counsel challenged Defendants' highly confidential designation as to three pages of the PMA: the cover page (Bates Number MDT0014583) and two pages within the section on Device Development and IDE Chronology (Bates Numbers MDT0014644 and MDT0014645). *Id.* at 1 & Ex A. [DE-76] at 2, 63-64. Defendants assert that the second and third pages at issue contain confidential clinical trial and device development information and that requiring page-by-page confidentiality designations within the PMA that in its entirety spans thousands of pages would be exceedingly burdensome, particularly where the PMA as a whole is widely considered confidential and not publicly available. *Id.* at 4-6. Plaintiff argues that

Defendants misrepresented to the court in their earlier motion to dismiss that the FlexCath® was part of the PMA Application for the CryoCatheter System and that making these pages public will prevent Defendants from making this misrepresentation in the future. Pl.’s Resp. [DE-84] at 2-3. Plaintiff also contends that there is no proprietary and trade secret information in these pages. *Id.* at 2.

The court agrees with Defendants that page-by-page confidentiality designations of a vast document that Plaintiff appears to concede is as a whole confidential would be inefficient and burdensome. *See Bass v. Stryker Corp.*, 669 F.3d 501, 511 (5th Cir. 2012) (“[C]ourts must keep in mind that much of the product-specific information about manufacturing needed to investigate [a medical device claim] fully is kept confidential by federal law.”) (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 178 & n.7 (N.D.N.Y. 2014) (“PMAs are kept confidential” and “[b]ecause the PMAs involve trade secrets and/or confidential commercial information provided to the government, they are not publicly available in their entirety.”) (citation omitted). Moreover, having reviewed the two substantive pages, the court finds that they contain sensitive development information. Ex A. [DE-76] at 63-64. The parties’ stipulated protective order in this case, which was adopted by the court, contemplates the designation of documents containing such information as “Highly Confidential.” *See* [DE-37] ¶ 5 (“The parties shall have the right to further designate Confidential documents or portions of documents relating to the development, manufacturing, or sale of catheter ablation therapy as ‘Highly Confidential.’”). Finally, the court’s order on Defendants’ motion to dismiss makes clear that the FlexCath® was not listed as part of the system or as a device approved as part of the PMA application process. The court stated,

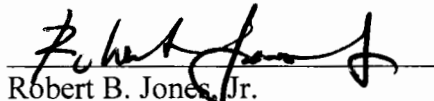
Plaintiff's claims rely on the use of the FlexCath® Steerable Sheath during Mr. Spilker's procedure. The documentation produced by FDA shows that the Arctic Front® Cryocatheter System went through the FDA's PMA process and was approved for use. The FDA clearly and repeatedly listed the devices that were part of that system, and the FlexCath® Steerable Sheath was not listed as part of the system or as a device approved as part of the PMA application process. Thus, the court finds defendants' preemption argument untenable.

Dec. 19, 2013 Order [DE-31] at 7-8. This publicly available document accomplishes the end Plaintiff seeks without divulging Defendants' confidential information. Accordingly, Defendants' motion is allowed.

III. CONCLUSION

For the reasons set forth above, Plaintiff's Motion to Extend Discovery [DE-69] is allowed in part and denied in part, Plaintiff's First Motion to Compel Discovery [DE-72] is allowed in part and denied in part, and Defendants' Motion for a Court Determination that Volume I of the Cryocatheter System's Pre-Market Approval Application is Properly Designated as Highly Confidential [DE-75] is allowed.

SO ORDERED, the 13 day of April 2015.


Robert B. Jones, Jr.
United States Magistrate Judge